

**Statement**

of the

**American  
Pharmaceutical  
Association**

*The National Professional Society of Pharmacists*

**Consumer Medication Information  
Food and Drug Administration  
Drug Safety & Risk Management  
Advisory Committee  
July 17, 2002**



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**Statement of the American Pharmaceutical Association (APhA)  
to the Food and Drug Administration's  
Drug Safety and Risk Management Advisory Committee  
Consumer Medication Information  
July 17, 2002**

Good afternoon. Thank you for the opportunity to present the views of the American Pharmaceutical Association (APhA), the national professional society of pharmacists. I am Tom Menighan, a long-time community pharmacist and home infusion practitioner. For the last two years, I have been involved in the delivery of health information and communication capabilities to consumers and pharmacists via the Internet. I am the immediate past president of APhA, and appearing today on the Association's behalf. We represent more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians.

APhA frequently partners with Federal agencies, consumer groups, the pharmaceutical industry, and others to develop and provide education for pharmacists and consumers. The Association did not receive funding to participate in today's meeting, and the views I am presenting are solely those of the Association and its membership.

We applaud the Food and Drug Administration (FDA) and our pharmacist members for the progress made in the provision of written materials to consumers. Yet, as evidenced in the Evaluation of Written Prescription Information Provided in Community Pharmacies, December 2001, many challenges remain. The biggest challenge, however, is not in making written information useful. Rather, it is in getting written information actually used by consumers. My comments today will focus on the role of consumer medication information (CMI) in pharmacist/patient discussions, the challenges to standardizing CMI, and recommendations for improvements.

***Consumer Medication Information***

Pharmacists are committed to improving patient health through the appropriate use of both prescription and over-the-counter medications. To ensure the safe and effective use of medications, pharmacists help patients manage their medications with patient education activities including written information and oral consultation. Written consumer medication information, the subject of today's meeting, is one method to provide patients with information on proper use of their medications, possible side effects and adverse reactions, and general information.

Pharmacists support efforts to provide patients with better information, including written CMI, about their drug therapy. Our profession has made great strides in this area. In 1992, less than 25% of patients received written patient information other than the prescription label and associated stickers.<sup>1</sup> Just three years later, a 1995 study showed that more than 55% of patients received written CMI.<sup>2</sup> And the latest study released last month by the FDA shows that more

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<sup>1</sup> David Kessler. Remarks made at the U.S. Pharmacopeial Convention. March 11, 1995.

<sup>2</sup> 60 FR at 44195.

than 89% of patients today receive CMI.<sup>3</sup> It is clear that pharmacy has taken the charge of distributing CMI very seriously. However, the results of the study also show that the quality of information distributed varies and did not meet the criteria evaluating “usefulness” 100% of the time.<sup>4</sup>

While we agree that many of the privately-generated patient package inserts or handouts in use today can be improved; determining the specific causes of insufficiencies in CMI and how to address them will require continued effort. One very concrete way of gaining improvements would be to more broadly publish the criteria used in the study and then to challenge vendors and publishers to meet or exceed the criteria.

We agree that usefulness is important and should be improved. Yet, no matter how well written patient information materials are, they are useless unless patients consider them important enough to adapt their behaviors based on that material and the guidance of their health professionals. Written information is an adjunct for communicating with patients—that primary mechanism continues to be one-on-one encounters between the health care professional and patient so that new information can be factored together with routine. This is especially true for older patients with multiple chronic medicines and confusing therapeutic regimens. Written information can support and enhance oral communications, but written information alone, without accompanying oral counseling, is insufficient to meet the needs of consumers and will do little to improve patient comprehension and compliance. Without the pharmacist emphasizing the importance of written information to individual patients, those patients will often treat the information the same way you treat the junk mail you throw away without reading.

As new studies are devised to evaluate CMI, we recommend that all settings that provide medications be evaluated, including outpatient hospital pharmacies, managed care pharmacies, mail service and Internet pharmacies, long-term care facilities, physicians’ offices, and others. How patients obtain medication information in these settings is equally important to ensuring safe and effective use.

### ***Customization – Not Standardization – Is the Answer***

It is important to note that while CMI developers should be encouraged to improve the quality of patient information, and that criteria for evaluation should be more broadly publicized, APhA will not support government regulations that would specify the content, precise language of the information, or design of CMI. Patient information must be tailored to each patient and used to supplement information provided by the pharmacist and other health care professionals— attempts to standardize the content of CMI would reduce our ability to provide information specific to the particular drug and the particular patient. Regulation of the content and design of CMI will not guarantee the quality of medication information. We should instead foster

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<sup>3</sup> Food and Drug Administration Talk Paper. “Success of Private Sector Patient Information with Prescription Medicines Assessed.” June 18, 2002.

<sup>4</sup> Food and Drug Administration Talk Paper. “Success of Private Sector Patient Information with Prescription Medicines Assessed.” June 18, 2002.

innovation that takes full advantage of technology and pharmacists' knowledge of their patients to create better educational experiences for consumers. Regulation may unintentionally reduce pharmacists' ability to provide patients with information customized to the individual patient for the individual product. Consumers will ask questions that bring the written information into their consciousness and lead to improved care. The ability to customize patient information is key.

Thousands of medications are on the market—each with unique chemical properties, risks and benefits of use. Further, knowledge usually advances faster than label changes. Vendors of written information should be encouraged to keep their written information contemporary. The information, and relative weights of various components that should be communicated to patients, will vary with each product. For example, proper storage instructions are more important for products subject to degradation or lack of effectiveness such as antibiotic suspensions reconstituted at the pharmacy. For other products, such as solid tablets, storage conditions may be less important. A patient with asthma on multiple drugs will be much more interested in information on interactions, contraindications and dosage adjustments to maintain proper care.

Customization of written information is an important key to creating useful information. Information specific to the patient—specific to their intended use of the product whether the use is FDA-approved or not—is far more valuable than a CMI pamphlet with regulated, inflexible content.

We understand that the Agency recognizes the progress made in distributing patient information and is not moving to regulate written CMI at this time.<sup>5</sup> The Association appreciates the Agency's decision to work with the pharmacy community and the private sector developers to improve the quality of written CMI. We strongly support the FDA's efforts to improve the appropriate use of medication through patient education activities and we are committed to improving the educational efforts of pharmacists with their patients. We are interested in working with other health professions, consumer organizations, and the FDA to ensure that patients receive AND USE the medication information they need—through oral communications with their pharmacist and prescriber—and through the distribution of quality written CMI.

Thank you for your consideration of the views of the nation's pharmacists.

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<sup>5</sup> Food and Drug Administration Information Advisory. Drug Safety and Risk Management Advisory Committee Briefing Information. July 17, 2002.